Citation:

Nickols-Richardson SM, Coleman MD, Volpe JJ, Hosig KW. Perceived hunger is lower and weight loss is greater in overweight premenopausal women consuming a low-carbohydrate/high-protein vs high-carbohydrate/low-fat diet. J Am Diet Assoc 2005; 105: 1433-1437.

PubMed ID: 16129086

Study Design:

Randomized Clinical Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effects of a low-carbohydrate/high-protein diet with a high-carbohydrate/low-fat diet on self-reported scores of hunger and cognitive eating restraint in overweight premenopausal women during a 6-week dietary intervention designed for weight loss.

Inclusion Criteria:

Overweight, premenopausal women, aged 32 - 45 years.

Exclusion Criteria:

Excluded if BMI < 25 or > 40, body weight loss of > 5 kg in previous year, self-reported menstrual cycle length of < 21 or > 35 days or disruption of menstruation during the past year, currently pregnant or lactating, physical activity of > 7 hours per week, current cigarette smoking, metabolic or endocrine diseases or disorders, and use of medications affecting metabolic or endocrine function.

Description of Study Protocol:

Recruitment

Not described.

Design

Randomized Clinical Trial.

Blinding used (if applicable)

Not used.

Intervention (if applicable)

Subjects consumed either low-carbohydrate/high-protein or high-carbohydrate/low-fat diet for 6 weeks.

Statistical Analysis

Data are reported for 12 women in low-carbohydrate group and 11 in high-carbohydrate group due to incomplete dietary recall data. A t test was conducted to compare mean BMI at baseline to ensure no significant difference in BMI after randomization of women to diet groups. Repeated measures ANCOVA were conducted to detect significant group x time interactions in body weight, BMI, hunger, cognitive eating restraint, and dietary intake across time.

Data Collection Summary:

Timing of Measurements

Fasting body weight and Eating Inventory completed at baseline, weeks 1 - 4 and week 6.

Dependent Variables

- Fasting body weight to nearest 0.1 kg
- Eating Inventory scored according to standard guidelines and hunger and cognitive eating restraint subscales examined
- Height measured to nearest 0.1 cm with stadiometer

Independent Variables

- Low-carbohydrate/high-protein diet (<20 g CHO/day for first 2 weeks, then increased 5 g/week to 40 g CHO/day at week 6, no caloric restriction) or high-carbohydrate/low-fat diet (1500-1700 kcals/day based on REE with 60% kcals from CHO, 15% from protein, 25% from fat). RD conducted all group educational sessions, with weekly educational and motivational sessions. 4-day food records completed at baseline and during weeks 1, 2, 4 and 6
- Usual physical activity levels were to be maintained and weekly physical activity recalls completed

Control Variables

Description of Actual Data Sample:

Initial N: 28 women

Attrition (final N): 28 women, although some dietary recalls removed for being incomplete. Low carbohydrate (n=13), high-carbohydrate (n=15)

Age: Low-carbohydrate: mean age 38.8 +/- 6.2 years, high-carbohydrate: mean age 40.1 +/- 6.3 years

Ethnicity: Not mentioned

Other relevant demographics:

Anthropometrics: Age, height, body weight, BMI and energy intake did not statistically differ

between groups at baseline.

Location: Virginia

Summary of Results:

	Low-Carb Baseline (n=12)	Low-Carb 6 weeks	High-Carb Baseline (n=11)	High-Carb 6 weeks
Energy (kcals)	2025 +/- 645	1420 +/- 374	2340 +/- 1236	1395 +/- 264
Carbs (g/day)	249 +/- 98	43 +/- 22	286 +/- 132	209 +/- 41
Protein (g/day)	75 +/- 22	94 +/- 29	89 +/- 20	63 +/- 16
Fat (g/day)	81 +/- 26	97 +/- 26	94 +/- 78	34 +/- 15
Carbs %	49 +/- 6	12 +/- 2	49 +/- 6	60 +/- 7
Protein %	15 +/- 3	26 +/- 4	15 +/- 4	18 +/- 4
Fat %	36 +/- 5	61 +/- 7	36 +/- 6	22 +/- 4

Other Findings

All women experienced a reduction in body weight ($P < 0.01$) but relative body weight loss was greater in the low-carbohydrate/high-protein vs high-carbohydrate/low-fat group at week 6 (5.7% vs 3.3%, $P < 0.05$).

Based on Eating Inventory scores, self-rated hunger scores decreased ($P < 0.03$) in the low-carbohydrate/high-protein group but not the high-carbohydrate/low-fat group from baseline to week 6.

In both groups, self-rated cognitive eating restraint increased ($P < 0.01$) from baseline to week 1 and remained constant to week 6.

Estimated average daily intake did not significantly differ between groups at any time point.

Author Conclusion:

A low-carbohydrate/high-protein diet intervention seems to be effective for body weight reduction over a 6-week period, as does a high-carbohydrate/low-fat diet. Overweight premenopausal women complying with a low-carbohydrate/high-protein diet may lose proportionately more body weight over a short-term period. Maintenance of body weight loss facilitated by a low-carbohydrate/high-protein diet must be further evaluated and compared with other weight loss diets with varied macronutrient compositions, particularly in relation to hunger and cognitive eating restraint ratings. Subjects complying with the low-carbohydrate/high-protein diet reported less hunger but similar cognitive eating restraint compared with women following high-carbohydrate diet. The impact of hunger and cognitive eating restraint on compliance with dietary interventions for body weight loss and continued weight-loss maintenance must be considered and included in weight loss programs.

Reviewer Comments:

Removal of incomplete records leaves small sample size. Recruitment not defined.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes